REMARKS

The Applicants request reconsideration of the rejection.

Claims 1, 4, and 6-10 are now pending.

Claims 1, 4 and 6-9 were rejected under 35 U.S.C. §103(a) as being anticipated by Rosenschein et al., US 6,113,558 (Rosenschein) in view of Ueberle, US 4,819,621 (Ueberle). The Applicants traverse as follows.

The present invention is directed to a therapeutic ultrasound system in which an ultrasonic transducer is controlled to irradiate therapeutic ultrasound to treat a region by heat coagulation. The therapeutic ultrasound is provided in significant part from a time of detecting an audible sound generated in the region to be treated, until the expiration of a time period set via an input unit. Importantly, the time of irradiation from the point of detection of the audible sound until the expiration of the input time is a time of continuous insonation.

The primary reference to Rosenschein discloses a therapeutic transducer and method which generates vibration sufficient to maintain cavitation at a desired location. The cavitation itself is the therapeutic application. Rosenschein adds a microphone to detect whether cavitation is or is not occurring. The microphone output can be fed to a data

processor, which can display a warning signal or deactivate the ultrasound device if the device is fully powered but no cavitation is being detected by the microphone. When the microphone output indicates cavitation, the output can be employed to permit the operator to reduce power to the transducer to obtain the minimal amount of power needed to sustain the cavitation.

In contrast, the present invention generates and applies ultrasound to perform a different sort of therapy than that taught by Rosenschein. Specifically, the present invention treats a region by heat coagulation. As noted above, Rosenschein irradiates therapeutic ultrasound for treatment by cavitation. Thus, at the outset, the person of ordinary skill learns nothing about the efficacies or parameters required for treating a region by heat coagulation, from the teachings of Rosenschein.

Furthermore, as noted above, the present invention requires control of the therapeutic ultrasound so that insonation is continuous from the time of detecting an audible sound in the region to be treated until the expiration of a continuous insonation time set via an input unit. Rosenschein, however, positively teaches away from continuous insonation, despite the statement to the contrary in the

present Office Action. In this regard, the Applicants have noted Column 3, lines 62-66, which state, "A transducer can be operated in a continuous mode or in a pulsed mode. In a continuous mode, the signal to the transducer is always causing the transducer to generate sufficient vibration to maintain cavitation at the desired location."

This passage was noted in the Office Action. However, the Office Action failed to note that the remainder of the patent distinguishes the continuous mode as being inferior to the pulsed mode. For example, Column 4, lines 35-47 state that transducer 110 receives signal 121 from generator 120 via electric wires 112. Signal 121 is formed with a plurality of energy pulses 122 of duration τ of sufficient amplitude to maintain cavitation, followed by "off" portions of insufficient amplitude to maintain cavitation. As stated in the paragraph, the duration of time between the beginning of successes pulses is referred to as pulse repetition period T, such that pulse duration τ is advantageously significantly smaller than pulse repetition T. Thus, continuous insonation is discarded as an advantageous mode.

Furthermore, Examples 21-27 disclosed in the patent describe various comparisons among pulsed modes and continuous modes, referring to Figs. 24-27. Note curve 608 of Fig. 24,

which shows comparatively insignificant cavitation for therapeutic effect. Note further Example 22, column 12, lines 53-54, which states that "relatively no cavitation generated from operation in the continuous mode at up to 20 watts" resulted.

In addition, Example 23 (Fig. 25) developed a curve 655 showing operation in the continuous mode, wherein an ultrasound threshold occurred at about 20 watts and there was no essentially no cavitation generated from the continuous mode operation at the power level (Column 12, lines 63-67). Similarly, Examples 24-26 showed ineffective treatment in the continuous mode (Column 13, lines 5-9: "Cavitation initiated in the range 15 to 20 watts for the pulse mode of operation, but not in the continuous mode operation, demonstrating advantages of pulsed operation in accordance with the invention;" Column 13, lines 15-20: "Continuous mode operation is shown as curve 665. The cavitation threshold occurred in the range 15 to 20 watts for the pulsed mode of operation, but not the continuous mode of operation, demonstrating advantages of pulsed operation in accordance with the invention;" Column 13, lines 25-31: "Continuous mode operation is shown by curve 674. A cavitation threshold occurred in the range of about 15 to 20 watts for pulsed

operation, but with less overall cavitation activity than for some of the longer pulsed durations. It is believed that the liquid medium requires a recovery period for optimum cavitation efficiency").

The secondary reference to Ueberle does not provide the teachings missing from Rosenschein. Specifically, Ueberle is applied as teaching a waveform analyzing unit which obtains a cross-correlation function between a waveform of a detected audible sound and a typical waveform of an audible sound previously obtained in a region to be treated as an indication of the occurrence of cavitation. However, Ueberle's teachings have limited applicability to the treatment taught by Rosenschein. Note that Ueberle is directed to a method and apparatus for detecting possible tissue injuries caused by cavitation during the medical application of high sonic energy, and specifically to prevent cavitation entirely or to prevent cavitation from damaging tissues that are not under treatment. The person of ordinary skill is thus, at most, led to modify Rosenschein so as to provide Ueberle's comparative signal analysis with respect to the output of Rosenschein's microphone. Ueberle does not teach that Rosenschein should be applied to treat tissue by heat coagulation, or to provide a time of continuous insonation following the detection of an

audible signal, the time of continuous insonation expiring in accordance with a time input via an input unit

Thus, the Applicants respectfully submit that the detection of audible sound, while common across the present invention and the applied references, is employed in a different way to achieve different results in the various methods and apparatus. In particular, the ultrasonic therapy of the present invention is controlled to irradiate therapeutic ultrasound on the region to be treated so as to coagulate by heat from the point of time of detection of the audible sound until the expiration of a time of continuous insonation input via an input unit. Thus, whereas the present invention makes it possible to secure the effect of coagulation without increasing the intensity of the ultrasound to be applied, while suppressing the emergence of side-effects due to overheating, Rosenschein teaches to use a microphone to obtain a feedback indicating cavitation, and to control an ultrasound device so as to deactivate the ultrasound if the device is fully powered without cavitation, or to reduce the power to the transducer in the event of cavitation so as to apply a minimal amount of power needed in order to sustain the cavitation, and Ueberle uses a microphone to detect cavitation

so as to prevent cavitation effects on tissue which should not be damaged by the cavitation.

Therefore, the Applicants submit that the person of ordinary skill would not find the invention obvious by attempting to modify Rosenschein in view of Ueberle.

New Claim 10 is a dependent claim that requires the sound detector to detect audible sounds in the range to 200 to 900 Hz. See, for example, Fig. 4 and Page 19, line 15 through Page 20, line 11 of the present specification.

The importance of this claim is that when therapeutic ultrasound is irradiated on the region to be coagulated by heat, the temperature in the tissue at the focal point rises from about 37°C to 100°C. Then, bubbles mainly composed of water vapor are radically generated inside the tissue. The bubbles expand in the narrow tissue, generating an audible sound in the range claimed.

As noted in the attached excerpt from Ultrasound: Medical Applications, Biological Effects, and Hazard Potential (Repacholi, ed.), when cavitation occurs in water or living tissue, a strong signal at the fundamental (2.7 MHz) and half-harmonic and weaker signals at the second, third, and higher harmonics, are detected. Particularly when cavitation is occurring in living tissue, a wider bandwidth centered at a

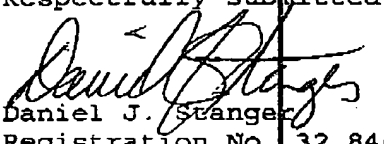
frequency below the half-harmonic spike is shown (see Fig. 9E). This bandwidth emission is seen in the range of about 500 kHz to 1.5 MHz. Insignificant emission is seen below 500 kHz.

In the case of Rosenschein, if therapeutic ultrasound at a frequency of 20 kHz is applied invasively to induce cavitation (Column 5, lines 28-41), the fundamental at 20 kHz and the 10 kHz half-harmonic would be strongly detected during the insonation. A strong emission below 1 kHz will not be expected in the case of Rosenschein.

Therefore, an audible sound detectable from coagulated tissue is based on an entirely different phenomenon than that of Rosenschein. Accordingly, Claim 10 is separately patentable over Rosenschein, whether taken individually or in combination with any other reference of record.

In view of the foregoing remarks and amendments, the Applicants request reconsideration of the rejection and allowance of the claims.

Respectfully submitted,



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